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DATE: 2/11/03 **TIME:** 3:35

TO: Select Agent Program **FAX#** 404-498-2265

FROM: EH&S - Cornell University

SPECIAL INSTRUCTIONS:

Comments on Interim Final Rule: Possession, Use & Transfer of Select Agents and Toxins.

This transmission includes 3 **page(s) plus 1 cover page. If there are any problems during transmission, or documents being received incomplete, please call us at 607-255-8200 and ask for** Robin .

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Environmental Health & Safety

February 11, 2003

Centers for Disease Control and Prevention
National Center for Infectious Diseases
Select Agent Program
1600 Clifton Road, MS E-79
Atlanta, GA 30333

RE: Proposed Interim Final Rule for Possession, Use, and Transfer of Select Agents

We are writing in response to the Centers for Disease Control and Prevention's solicitation for comments on 42 CFR Part 73, 7CFR Part 331, and 9 CFR Part 121, Interim Final Rule, Possession, Use, and Transfer of Select Agents and Toxins published in the Federal Register, Vol. 240, No. 67 on Friday, December 13, 2002.

Cornell University's Department of Environmental Health and Safety (EH&S) is providing general and specific comments and recommendations; these are attached.

EH&S also supports the comments and recommendations for 42 CFR Part 73 submitted by the Howard Hughes Medical Institute (HHMI) and the Council on Government Relations (COGR).

Specifically, the basis for our support and endorsement is that the recommendations will ensure the appropriate availability of biological agents and toxins for research, education, and other legitimate purposes. Also, it will make the safeguard and security requirements for persons possessing, using, or transferring a listed agent or toxin, risk-based. These provisions are requirements of the "Public Health Security and Bioterrorism Preparedness and Response Act of 2002." Generally, the adoption of the recommendations of the HHMI and the COGR will lessen the administrative burden of the Final Rule, allow for an effective performance-based security plan, and ensure the relevance of the Final Rule to the biomedical research environment.

We appreciate the opportunity to comment on the Interim Final Rules and encourage the CDC and APHIS to consider and implement changes to further clarify and simplify these regulations to ensure consistency and facilitate compliance by those affected by them.

Sincerely.

Andy Garcia-Rivera
Director

Frank A. Cantone
Biological Safety Officer

Enclosures: Comments on Interim Final Rule; Possession, Use and Transfer of Select Agents and Toxins

COMMENTS ON

CDC & APHIS INTERIM FINAL RULE

POSSESSION, USE, AND TRANSFER OF SELECT AGENTS AND TOXINS

Cornell University
Department of Environmental Health and Safety
February 11, 2003

We offer the following comments in addition to those our colleagues in academia and industry have already provided.

1. The CDC and APHIS have two "front doors" to handle the interim rules. A number of academic institutions will be covered by both regulatory entities. To facilitate compliance for the regulated community, we recommend that both agencies create ONE "front door" to centralize and manage the entire application, registration, and compliance process. This will result in greater efficiency and consistency, and provide more timely guidance.

2. The CDC and APHIS list an aggressive compliance schedule that depends on a number of agencies performing tasks that may not be completed in time. For example, the Department of Justice security risk assessment process is not defined, lacks a completed assessment and notification timeframe or schedule, and does not include an explanation as to what happens if the requirements are not met in time. In other words, what is the impact to the timely conduct of research with select agents and toxins? Quick turnaround of security risk assessments is critical. What accountability will be built-in to ensure that the Justice Department provides a rapid turnaround for security risk assessments, and will there be an adequate appeals process to address possible problems or inaccuracies? Will the security risk assessment for an investigator be transferable from one entity to another?

3. The performance standard nature of the interim regulations is generally good, yet there are parts in which specific security requirements are cited. Further clarification and definition of acceptable security elements is necessary to ensure that investment in a security plan is acceptable to the regulators, and is not rejected after investments have been made. We recommend that the CDC and APHIS consider a pre-qualification process, with timely decision notification for security plans.

4. Many universities can be spread out within a city or town and may have operations in other counties within a State, in a different State, or even abroad (where an entity wants the same operating procedures and regulations observed). Therefore, how many responsible officials are necessary for such an entity? Is a model of one central responsible official and several alternate responsible officials located outside of a main campus a viable option? We recommend that a single responsible official, under a single entity administration, be permitted to designate alternate responsible officials to cover entity operations outside of its central campus.

5. We are concerned about the transfer of select agents from one entity to another. If, for example, an entity follows all of the requirements for possessing and using a select agent and then offers the package to a commercial shipper (e.g., FedEx, Airborne Express, DHL) for transfer. According to IATA/DOT regulations, this package will be clearly labeled with the proper select agent name and biohazard designation, complete with all the dangerous goods paperwork. The entity will give the package to a person working for a carrier company, thus providing the carrier's representative with "direct access" to the select agent or toxin. Is this permissible? Will the person receiving the package for transport be required to have a DOJ security risk assessment? We assume the answer is yes, and if so, what process does CDC/APHIS or DOT have to reassure the entity and its responsible official that the person transporting the package has an approved security risk assessment? Will the

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entity have to provide the names of the carrier and its employees to the DOJ since the carrier representative will have access to the agent as defined in the interim rules?

6. Access is, and continues to be, a difficult concept to comprehend. It is imperative that access be clearly defined so there is no misunderstanding as to whom access applies and under what conditions. The definition of access provided and recommended by the HHMI, as "the ability to gain physical control of select agents and toxins" is most appropriate and should be incorporated. This allows entities to define the "areas" that require control and determine the most appropriate security measures for their institution and circumstance. Those personnel covered by this definition would be only those individuals who actually handle and use select agents and toxins.

7 The term entry should be used for those situations where an individual has to enter the select agent laboratory or designated storage area to perform their duties (e g , custodial, maintenance, safety, security work and the like). Entry does not constitute access (read the definition above). A definition for entry is necessary along with minimum elements for a background check that the entity can perform (i.e., not a DOJ check). We recommend that entry be defined as the ability to perform non-research related duties in support of the select agent operations by entity staff who have undergone an entity security background check in accordance with requirements. Individuals who do not have approved DOJ or institutional security background checks may only enter the select agent laboratory as long as they are escorted at all times during their visit by a staff member approved by DOJ and designated by principal investigator in charge of the select agent/toxin laboratory.

Note: if the definition of entry is then included, this change must be reflected, as appropriate, throughout the regulations (e.g., biosecurity plan, responsibilities of the RO, record keeping, etc.).

8. Private academic institutions may be "owned" by a corporation and controlled by a Board of Trustees. Does it mean that all individuals in this "owning or controlling" role need to undergo a DOJ security risk assessment even though they are so removed from the process and the select agent/toxin laboratory? These regulations need to clearly define who "owns or controls" the entity, and which owner(s) or controller(s) need the security risk assessment.

9. When and what constitutes identification of a select agent? For example, is a PCR test from a gene, or a series of biochemical assays adequate, especially if there aren't recognized standards for that agent or within a particular field of study? Given the serious implications of an "identification", presumptive diagnosis, or even suspicion of a select agent, we don't believe it is merely a trivial or academic question. When is the agent "identified"? Are there provisions in place for confirmatory diagnosis or "identification" by another entity or Federal agency? Will the entity have the ability to transfer the agent in question, yet retain a portion of the sample, and not be in violation of the destruction/transfer requirements of the regulations?

Similarly, when and what is defined as a natural environment? For example, are milk samples that contain *Coxiella burnetii*, or macque tissue with Herpes B virus a natural environment? Is an entity required to report the "identification" of a select agent from these samples, or is the entity exempted based on natural environment? We would appreciate some clarification.